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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/695,295 | 10/28/2003 | Joseph A. Gonzales | A-2966-AU | 4188 |
| 21378 7590 04/15/2008 APPLIED MEDICAL RESOURCES CORPORATION 22872 Avenida Empresa Rancho Santa Margarita, CA 92688 | | | | |
| EXAMINER | | | | |
| VU, QUYNH-NHU HOANG | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3763 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/695,295

Applicant(s)

GONZALES ET AL.

Examiner

QUYNH-NHU H. VU

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-893)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Response to Amendment

Amendment filed on 12/06/06 has been entered.

Claims 1-10 are present for examination.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **seal material 70** (page 11, lines 8); **cylindrical walls 90, 92** (page 11, lines 21-21); **proximal housing portion 75b** (page 14, line 21); **treads 130** (page 16, line 9).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because:

Fig. 6 does not show clearly which element denotes for the plug 81a and the node 116.

Does the node 116 having some particles or many protrusions to make the surface more roughness?

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a

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drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinstein et al. (US 5,460,616).

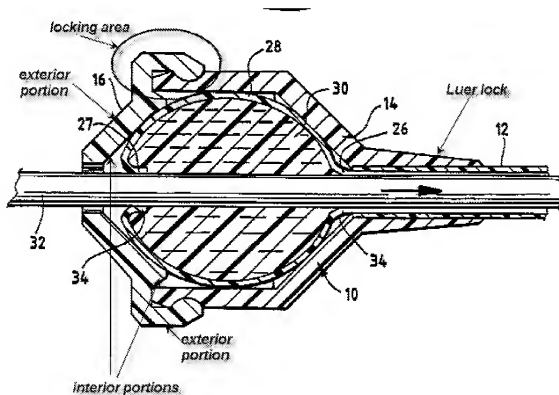
Weinstein discloses, see Fig. below, a housing including a proximal housing portion and a distal portion 14 to define a gel cavity 30. a seal material disposed in the gel cavity, the seal member including a gel having non-compressible characteristics; a proximal guide tube 16 extending axially proximally from the proximal housing portion; the proximal guide tube facilitating insertion of a surgical instrument into the seal material; a distal guide tube (closes to Luer lock arrow) extending axially distally from the distal housing portion, the distal guide facilitating retrograde insertion of the surgical instrument into the surgical seal; wherein the proximal guide tube includes exterior portions extending proximally of the proximal housing portion and interior portions extending distally of the proximal housing portion. Weinstein

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discloses a luer lock (see Fig. below) coupled to the distal guide tube 14 or 12, the distal guide tube being included within the luer lock.

Regarding claim 6, Weinstein further discloses a node 27. Because Applicant does not clearly explain the purpose or function of node in the device, nor show the node clearly in Figs. 6-7. Therefore, Examiner interprets the element 27 as a node.

Regarding claim 10, Weinstein discloses a first housing portion 16, a second housing portion 14; a gel 30 disposed within the gel cavity and having properties including flowability and incompressibility, the gel having characteristics for creating a pressure on the instrument to form a seal with the instrument, and means for moving the second housing portion relative to the first housing portion to increase the pressure of the incompressible gel on the instrument and create a locking force tending to inhibit movement of the instrument relative to the valve (see Fig. below, or col. 1, line 47)



Claims 1, 4-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gravenor et al. (US 5,630,417).

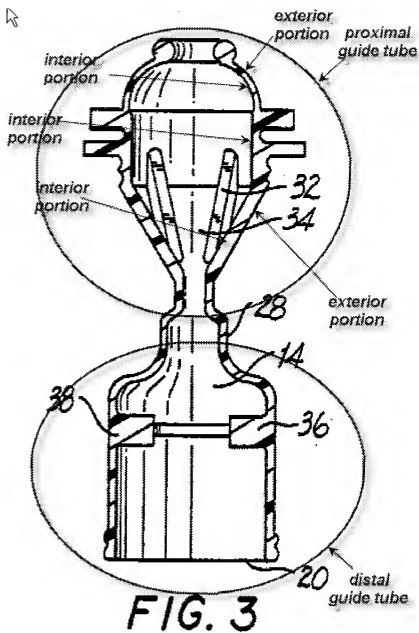
Gravenor discloses a surgical valve having an axis extending between a proximal and a distal end comprising:

a housing including a proximal housing portion 26 and a distal portion 18 to define a gel cavity 42. a seal material disposed in the gel cavity, the seal member including a gel having non-compressible characteristics; a proximal guide tube 16, 22, 26, 28 extending axially proximally from the proximal housing portion; the proximal guide tube facilitating insertion of a surgical instrument into the seal material; a distal guide tube 18, 20 extending axially distally from the distal housing portion, the distal guide facilitating retrograde insertion of the surgical instrument into the surgical seal; wherein the proximal guide tube includes exterior portions extending proximally of the proximal housing portion and interior portions extending distally of the proximal housing portion.

Regarding claims 4-5, the seal material defines 42 defines an axial channel through the gel, and the proximal guide tube contacts the seal material around the axial channel at the proximal end of the valve, see Fig. 7; the seal material and the first housing portion form a subassembly free of a circumferential seal between the seal material and the first housing portion; and subassembly to form a circumferential seal between the gel and the first housing portion; the proximal guide tube applies a force to seal material in subassembly to form a circumferential seal between the gel and the first housing portion, see Fig. 7.

Regarding claims 6-9, Gravenor discloses that a first housing portion defining a gel cavity; a node 32 (Fig. 3) or 46 (Figs. 10, 14-16) an axial channel; a subassembly including the seal material disposed in the gel cavity; a second housing portion disposed juxtaposition to the first housing portion and applying a force to the seal material in the subassembly, the force being of a magnitude sufficient to place the channel of the seal material in a closed state (Figs. 8-9); wherein the guide tube (proximal guide tube) contacts the node 32 or 46 of the seal material to apply the force to seal material (Figs. 8-16).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gravener in view of Mollenauer et al. (US 5,514,109).

Gravener discloses the valve as described above in reference to claim 1. Gravener fails to explicitly describe a luer lock coupled to the distal housing portion.

Mollenauer describes a similar surgical valve with a luer lock 242, see Fig. 11.

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the surgical valve of Gravener by incorporating a luer lock of the type taught by Mollenauer in order to attach the tubing to the housing.

Response to Arguments

Applicant's arguments filed 12/06/06 have been fully considered but they are not persuasive.

Weinstein's device

1. Applicant argues that the Weinstein does not teach a proximal guide tube having exterior portions extending proximally of the proximal housing portion and interior portions extending distally of the proximal housing portion.

In response, Examiner clearly point out in Fig. 3 above.

2. Applicant argues that no reference is made to an axial channel cavity, nor a node in the sealing material (indeed, a valve designed to open upon application of pressure by an instrument penetrating the sheath would not be likely to facilitate placing an axial channel in a closed state).

In response, Because Applicant does not clearly explain the purpose or function of node in the device, nor show the node clearly in Figs. 6-7. Therefore, Examiner interprets as broadly that the element 27 as a node. Furthermore, Fig. 3 clearly shows that the sealing material having axially channel when instrument facilitate placing an axial channel.

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In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a valve designed to open upon application of pressure by an instrument penetrating the sheath would not be likely to facilitate placing an axial channel in a closed state) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

3. Applicant argues that Weinstein does not describe means for moving the second housing portion axially relative to the first housing portion to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve.

In response, device of Weinstein clearly shows in Fig. 3 that the first and second housing portion 14, 16 engaged to each other and one skill in the art would recognize that it will produce or increase the pressures of the gel on the instrument and there a locking force to engage the first and second portion together to inhibit movement of the instrument relative to the valve (see Fig. above)

Garvener's device:

1. Applicant argues that the element 22 of Gravener as a "proximal opening" rather than as a tube Gravener; there is no proximal guide tube in Gravener's device,

In response, according to www.answers.com define the tube: as a hollow cylinder, especially one that conveys a fluid or function as a passage. Device of Garvener including a hollow cylinder and able to convey a fluid or function as a passage also. See Fig above.

2. Applicant argues that Gravener does not teach a proximal guide tube having exterior portions extending proximally of the proximal housing portion and interior portions extending distally of the proximal housing portion.

In response, please see Fig. above.

3. Applicant argues that no reference is made to an axial channel cavity, nor to a node in the sealing material.

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In response, Applicant does not clearly disclose the node or function of the node. Furthermore, Applicant does not show clearly the node in Figs. 6-7, therefore, Examiner interprets broadly that the node is as protuberance, swelling, a knob, or a knob. Therefore, element 32 or 46 can be read as a node.

Gravener clearly discloses that the seal material having an axial channel (Figs. 6-16).

4. Applicant argues that no teaching or suggestion in Mollenauer of such a guide tube.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Examiner clearly point out that the guide tube show in Gravener's device.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner

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